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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/645,321

Applicant(s)

KOIZUMI ET AL.

Examiner

Manjunath N Rao

Art Unit

1652

-- Th MAILING DATE f this communication appears on the cover she t with the corr spondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-16 are currently pending in this application.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vann(a) et al. (Glycobiology, 1997, Vol. 7(5):697-701), or Vann(b) et al. (J. Biol. Chem., 1987, Vol. 262(36):17556-62) and Staesche(a) et al. (J. Biol. Sci., 1997, Vol. 272(39):24313-24318) or Staesche(b) et al. (J. Biol. Sci., 1997, Vol. 272(39):24319-24324). Claims 1-5 and claims 6-16 depending from claims 1-6 are drawn to a process of producing N-acetylneuraminic acid (NANA) which comprises allowing a culture of a microorganism having NANA aldolase activity or NANA synthetase activity or a treated matter of the culture, a culture of a microorganism capable of producing pyruvic acid or a treated matter culture when a microorganism having NANA aldolase activity is used in the step above, or culture of a microorganism capable of producing phosphoenol pyruvic acid or a treated matter of the culture when a microorganism having NANA-synthetase activity is used in the first above step, N-acetyl mannosamine and an energy source which is necessary for the formation of pyruvic acid or PEP to be present in an aqueous medium to form and accumulate NANA in the aqueous medium and recovering NANA from the aqueous medium.

Vann(a) et al. teach that NANA synthetase catalyzes the formation of NANA as indicated by its coupling to the CMP-NeuAc synthetase reaction. The reference also teaches that the enzyme condenses Mannosamine and Phosphoenolpyruvic acid (PEP). The reference indicates

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that it is the first time that anyone has demonstrated an aldolase-independent sialic acid synthetase activity in E.coli.

Vann(b) et al. teach the purification, properties and genetic location of above enzyme in E.coli K1.

Staesch(a) et al. teach that biosynthesis of NANA is initiated by the action of UDP-N-acetylglucosamine 2-epimerase and N-acetylmannosamine kinase and that the formation of NANA starts by the conversion of N-acetylglucosamine to N-acetylmannosamine in the presence of an energy donor such as ATP. In fact Staesch et al. teach that the biosynthesis of NANA is initiated and regulated by a key enzyme UDP-N-acetylglucosamine 2'-epimerase in rat liver cells. The reference provides the isolation and characterization of a cDNA clone of the epimerase in COS cells. However, one of ordinary skill in the art could also express the same in any prokaryotic cell such as E.coli also.

With all the above information found in the prior art and also due to the great commercial demand for sialic acid it would have been obvious to one of ordinary skill in the art at the time this invention was made to bring together all the above information and host cells expressing the above enzymes or their culture matter of host cells expressing the above enzymes and develop a method for synthesis of sialic acid. Due to the important industrial application one would be motivated to develop a method for manufacture of large amounts of sialic acid. One of ordinary skill in the art would have a reasonable expectation of success as Vann et al. teach the basic step of sialic acid biosynthesis and Vann et al. provide the cDNA clone and the regulatory details of sialic acid biosynthesis in cells.

Therefore, the claims 1-16 would have been *prima-facie* obvious to one of ordinary skill in the art.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is


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(703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao. Ph.D.
October 12, 2001


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1652